

January 26, 2023



Tonix Pharmaceuticals Announces Presentation of Licensed Antiviral Drug Technology at the 2nd Wnt & β -catenin Targeted Drug Development Conference

Oral Presentation Describes Activity of Wnt/ β -catenin Signaling Pathway Inhibitors Against SARS-CoV-2 in Cell Culture and in an Animal Model

CHATHAM, N.J., Jan. 26, 2023 (GLOBE NEWSWIRE) -- Tonix Pharmaceuticals Holding Corp. (Nasdaq: TNXP) (Tonix or the Company), a clinical-stage biopharmaceutical company, today announced that Tom Hobman, Ph.D., Professor of Cell Biology, University of Alberta, presented data from his laboratory at The University of Alberta during a presentation at the 2nd Wnt & β -catenin Targeted Drug Development Conference held in Boston, Mass., on January 26, 2023. The oral presentation titled, "**Targeting the Wnt/ β -catenin pathway as a broad-spectrum antiviral strategy**," includes research sponsored by Tonix Pharmaceuticals focused on the development and testing of Wnt/ β -catenin signaling pathway inhibitors as broad-spectrum antivirals against SARS-CoV-2 and other emerging viruses. Tonix has previously announced that it exercised an option to license the antiviral technology platform. A copy of the presentation is available on the Tonix Pharmaceuticals corporate website at www.tonixpharma.com.

"Antiviral therapeutics are needed to mitigate the effects of SARS-CoV-2 and future coronavirus outbreaks, and Professor Hobman's work is designed to facilitate the identification and testing of novel broad-spectrum antiviral drugs," said Seth Lederman, M.D., Chief Executive Officer of Tonix Pharmaceuticals. "Professor Hobman presented data showing that inhibition of Wnt/ β -catenin pathway induces peroxisomes and enhances interferon response during viral infection, significantly reducing SARS-CoV-2 replication *in vitro* and *in vivo*."

"For future pandemics, the scientific community must be ready with an arsenal of easily self-administered drugs that can be tested in rapid, efficient clinical trials immediately after the causative viral agent is identified," said Professor Tom Hobman. "The research collaboration between Tonix and The University of Alberta is focused on the development and testing of Wnt/ β -catenin signaling pathway inhibitors as broad-spectrum antivirals against SARS-CoV-2 and other emerging viruses."

Tonix Pharmaceuticals Holding Corp.*

Tonix is a clinical-stage biopharmaceutical company focused on discovering, licensing, acquiring and developing therapeutics to treat and prevent human disease and alleviate

suffering. Tonix's portfolio is composed of central nervous system (CNS), rare disease, immunology and infectious disease product candidates. Tonix's CNS portfolio includes both small molecules and biologics to treat pain, neurologic, psychiatric and addiction conditions. Tonix's lead CNS candidate, TNX-102 SL (cyclobenzaprine HCl sublingual tablet), is in mid-Phase 3 development for the management of fibromyalgia with a new Phase 3 study launched in the second quarter of 2022 and interim data expected in the second quarter of 2023. TNX-102 SL is also being developed to treat Long COVID, a chronic post-acute COVID-19 condition. Tonix initiated a Phase 2 study in Long COVID in the third quarter of 2022 and expects interim data in the third quarter of 2023. TNX-1300 (cocaine esterase) is a biologic designed to treat cocaine intoxication and has been granted Breakthrough Therapy designation by the FDA. A Phase 2 study of TNX-1300 is expected to be initiated in the first quarter of 2023. TNX-1900 (intranasal potentiated oxytocin), a small molecule in development for chronic migraine, is expected to enter the clinic with a Phase 2 study in the first quarter of 2023. TNX-601 ER (tianeptine hemioxalate extended-release tablets) is a once-daily formulation of tianeptine being developed as a potential treatment for major depressive disorder (MDD) with a Phase 2 study expected to be initiated in the first quarter of 2023. Tonix's rare disease portfolio includes TNX-2900 (intranasal potentiated oxytocin) for the treatment of Prader-Willi syndrome. TNX-2900 has been granted Orphan Drug designation by the FDA. Tonix's immunology portfolio includes biologics to address organ transplant rejection, autoimmunity and cancer, including TNX-1500, which is a humanized monoclonal antibody targeting CD40-ligand (CD40L or CD154) being developed for the prevention of allograft and xenograft rejection and for the treatment of autoimmune diseases. A Phase 1 study of TNX-1500 is expected to be initiated in the first half of 2023. Tonix's infectious disease pipeline includes a vaccine in development to prevent smallpox and monkeypox, TNX-801, a next-generation vaccine to prevent COVID-19, TNX-1850, a platform to make fully human monoclonal antibodies to treat COVID-19, TNX-3600, and humanized anti-SARS-CoV-2 monoclonal antibodies, TNX-3800, recently licensed from Curia. TNX-801, Tonix's vaccine in development to prevent smallpox and monkeypox, also serves as the live virus vaccine platform or recombinant pox vaccine (RPV) platform for other infectious diseases. A Phase 1 study of TNX-801 is expected to be initiated in Kenya in the second half of 2023.

** All of Tonix's product candidates are investigational new drugs or biologics and have not been approved for any indication.*

This press release and further information about Tonix can be found at www.tonixpharma.com.

Forward Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate," "expect," and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, risks related to the failure to obtain FDA clearances or approvals and noncompliance with FDA regulations; delays and uncertainties caused by the global COVID-19 pandemic; risks related to the timing and

progress of clinical development of our product candidates; our need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and substantial competition. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2021, as filed with the Securities and Exchange Commission (the “SEC”) on March 14, 2022, and periodic reports filed with the SEC on or after the date thereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date thereof.

Contacts

Jessica Morris (corporate)
Tonix Pharmaceuticals
investor.relations@tonixpharma.com
(862) 904-8182

Olipriya Das, Ph.D. (media)
Russo Partners
Olipriya.Das@russopartnersllc.com
(646) 942-5588

Peter Vozzo (investors)
ICR Westwicke
peter.vozzo@westwicke.com
(443) 213-0505



Source: Tonix Pharmaceuticals Holding Corp.